Department of Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes
December 08, 2015

Board Members:
Present:

Zail Berry, MD
Clayton English, PharmD
Janet Farina, RPh
Louise Rosales, NP
Michael Biddle, PharmD
James Marmar, RPh
Patrica King, MD

Absent:

Staff:
Michael Ouellette, RPh, GHS/Change HealthCare
Laureen Biczak, DO, GHS/Change HealthCare
Mary Beth Bizzari, RPh, DVHA
Nancy Hogue, PharmD, DVHA
Stacey Baker, DVHA
Jennifer Egelhof, DVHA
Jason Pope, DVHA
Laurie Pedlar, RPh, GHS/Change HealthCare
Scott Strenio, MD, DVHA

Guests:
Rita Baglini, APS Health Care
Mario Carnovale, Novartis
Christine Dube, MedImmune
Rod Francisco, Sunovion
David Halpin, AstraZeca
Kristen Bruno-Doherty, AstraZeneca
Adam Denman, GSK
Darren Keegan, Allergan
Brad Martin, Lundbeck
Brenda Pennels, J&J
Arlene Price, Janssen
Marjory Levey, UCB
Hannah Parker, AstraZeneca
Amy Tornasello, Mylan
Lance Nicholls, Pfizer
Marie Roche, Pfizer
Susan Donnelly, Pfizer
Scott Williams, J&J
Gillian Stephens, AstraZenca
Maggie Glassman, Alkermes
Stew Hoover, UCB

The meeting was called to order at 6:36pm. The first order of business was to elect a new chair. The board elected Louise Rosales, NP.

1. Executive Session:

- An executive session was held from 6:00 p.m. until 6:36 p.m.

2. Introductions and Approval of DUR Board Minutes:

- Introductions were made around the table.
- The October meeting minutes were accepted as printed.

3. DVHA Pharmacy Administration Updates: Nancy Hogue, PharmD, DVHA

- Three more physicians are currently pending approval for the board.
- Some of the State of Vermont staff offices will be relocating to Waterbury. It was asked if the board members were interested in having some of the meetings at the new location. After discussion, it decided that this topic will be brought up again in January once the three new members have started. Members of the board felt that the percentage of meetings held in the new location should be proportionate to the number of members living/practicing closer to Waterbury.
- Notice was provided regarding the availability of the Pharmacy Best Practices and Cost Control Report which is due annually to the Health Reform Oversight Committee. It is available via this link: http://legislature.vermont.gov/assets/Legislative-Reports/Pharmacy-Best-Practices-and-Cost-Control-Report-2015-Final.pdf . Nancy will distribute the link to Board members.

4. Medical Director Update: Scott Strenio,MD, DVHA

- No update at this time.

5. Follow-up Items from Previous Meetings: Michael Ouellette, RPh GHS/Change Healthcare and Laureen Biczak, DO GHS/Change Healthcare

a) Natpara clinical criteria

- Natpara: diagnosis of hypocalcemia secondary to hypoparathyroidism (but NOT acute post-surgical hypoparathyroidism within 6 months of surgery) **AND**
- Natpara PA form must be completed and clinical and lab documentation supplied **AND**
- Must be prescribed by an endocrinologist **AND**
- Must be documented by **ALL** of the following:
  - History of hypoparathyroidism >18 months **AND**
  - Biochemical evidence of hypocalcemia **AND**
  - Concomitant serum intact parathyroid hormone (PTH) concentrations below the lower limit of the normal laboratory reference range on 2 test dates a least 21 days apart within the past 12 months **AND**
- No history of the following:
  - mutation in CaSR gene **OR**
  - pseudohypoparathyroidism **OR**
  - a condition with an increased risk of osteosarcoma **AND**

- Hypocalcemia is not corrected by calcium supplements and preferred active forms of vitamin D alone **AND**
- Patients must be taking vitamin D metabolite/analog therapy with calcitriol ≥0.25 µg per day OR equivalent **AND**
- Must be taking supplemental oral calcium treatment ≥ 1000 mg per day over and above normal dietary calcium intake **AND**
- Serum calcium must be ≥ 7.5 mg/dl prior to starting Natpara **AND**
- Serum thyroid function tests and serum magnesium levels must be within normal limits **AND**
- Documentation of creatinine clearance > 30 mL/min on two separate measurements **OR** creatinine clearance > 60 mL/min AND serum creatinine < 1.5 mg/dL

Recommendation: The recommendation is to accept the above clinical criteria.

Board Decision: The Board unanimously approved the above recommendation.

b) Therapeutic Drug Classes/PDL 2016 Changes Michael Ouellette, RPh GHS/Change Healthcare and Laureen Biczak, DO GHS/Change Healthcare

- Platelet Aggregation Inhibitor/ Intermittent Claudication
  - Recommendation to move Brilinta® to preferred and remove the clinical criteria on Brilinta®.

  The Board unanimously approved the above recommendations

- ADHD and Narcolepsy Cataplexy
  - Recommendation to move Dexmethylphenidate to preferred.
  - Recommendation to move Guanfacine ER to preferred.
  - Recommendation to remove all of Intuniv clinical criteria except patient must have had a documented intolerance to generic guanfacine ER.

  The Board unanimously approved the above recommendations

- Analgesics Long Acting
  - Recommendation to move Butrans® Transdermal System to preferred and remove the clinical criteria on Butrans®. Quantity limits of 2 patches per 14 days will remain in effect.
  - Recommendation to move Embeda® to preferred. Quantity limits of 2 capsules per day will apply.

  The Board unanimously approved the above recommendations

- Anticoagulants, Injectables
  - Recommendation to move Enoxaparin to preferred.
  - Recommendation to move Lovenox® to non-preferred and update the brand/generic change in the clinical criteria.

The Board unanimously approved the above recommendations

- Antidiabetics- Non Insulin
    - Recommendation to move Tanzeum® to preferred after clinical criteria are met.
        - Clinical Criteria: Patient has a diagnosis of Type 2 diabetes AND patient is at least 18 years of age AND patient has documented side effect, allergy, or treatment failure with Metformin.
    - Recommendation to move Farxiga® to preferred.

The Board unanimously approved the above recommendations

- Antimigraine Triptans
    - Recommendation to move Relpax® to preferred and update the criteria to reflect change.
    - Recommendation to move Rizatriptan to preferred and update the criteria to reflect change.
    - Recommendation to move Naratriptan to non- preferred
        - Clinical Criteria: Patient has had a documented side effect, allergy, or treatment failure to Sumatriptan, Relpax, and Rizatriptan or Rizatriptan ODT.

The Board unanimously approved the above recommendations

- Lipotropics
    - Recommendation to move Zetia® to preferred and remove the clinical criteria.

The Board unanimously approved the above recommendations

- Multiple Sclerosis
    - Recommendation to move Gilenya® to preferred and remove the clinical criteria.

The Board unanimously approved the above recommendations

- Opthalmics
    - Recommendation to move Tobradex® suspension and ointment to preferred.
    - Recommendation to move Tobramycin w/Dexamethasone to non- preferred.
        - Clinical Criteria: The patient has had a documented intolerance with brand Tobradex.
    - Recommendation to move Besivance® to preferred.
    - Recommendation to move Neomycin/Polymyxin w/ Hydocortisone oint to non-preferred.
        - Clinical Criteria: The patient has had a documented intolerance with brand Tobradex.
    - Recommendation to move Lotemax® oint(pres. free) to preferred and remove the clinical criteria.
    - Recommendation to move Lotemax® gel and sol to preferred.
    - Recommendation to move Simbrinza® to preferred and remove the clinical criteria.

- Recommendation to move Acular LS® to non-preferred.
    - Clinical Criteria: The patient has had a documented side effect, allergy, or treatment failure to Acular.

The Board unanimously approved the above recommendations

- Pulmonary Agents
    - Recommendation to move Advair® Diskus to non-preferred. Current users as of 01/01/2016 will be allowed a 90 day grace period to transition to preferred Advair® HFA.

The Board unanimously approved the above recommendations

- Renal Disease Phosphate Binders
    - Recommendation to move Phoslyra® oral solution to preferred and remove the clinical criteria.

The Board unanimously approved the above recommendations

6. Retro DUR/DUR: Michael Ouellette, RPh GHS/Change Healthcare and Laureen Biczak, DO GHS/Change Healthcare

a) Testosterone Update

- It is recommended that total testosterone levels be measured prior to therapy and 2-3 months after initiation of therapy and then be monitored for 6-12 months to ensure the level is stable and then when there are symptoms or a dose change. Information from the October 20, 2015 DUR meeting was presented to review why the additional information on the prescribers was requested**.** The new data demonstrated there were 245 unique prescribers of testosterone in the time frame studied. 81 prescribers accounted for 5 or more prescriptions of testosterone during this period. There were 101 prescribers who had a least one member with potentially missing testosterone levels. 8 providers were the prescribers for more than 2 members who did not have the appropriate testosterone levels found in claims data. The board members stated that, upon reviewing the names of the prescribers, some may be working with the transgender community and it is possible that testosterone use in this setting may not require levels.

Recommendation: The original GHS recommendation was to do a record review from 2-3 members from each of the listed providers, specifically asking for chart notes and lab tests in the time frame that was studied. However, upon finding that some of these prescribers may be treating the transgender community suggests that levels may not be indicated.

Board Action: After the Board's discussion, Scott Strenio,MD, DVHA offered to give some of the top prescribers a call to get more information about what standard they are using with regard to testosterone therapy.

b) Present multiple benzo analysis including sedative/hypnotic (Z drugs)

- During the initial analysis for this period, there were 766 members on multiple benzodiazepines, 747 on two, 18 on three, and one member on 4. After refining the analysis to eliminate those members transitioning from one benzodiazepine to another benzodiazepine, the total number of users identified was narrowed to 45 members. These 45 members had a total of 71 prescribers identified for prescribing the benzodiazepines of which 23 members had multiple prescribers. We incorporated the Z drugs into the previous analysis to identify members with benzodiazepine in combination with Z drugs. We identified 338 members who had multiple prescriptions of either multiple benzodiazepine or benzodiazepine with Z drugs. The 338 members had a total of 369 prescribers . Of those prescribers, one was prescribing for 12 patients, one with 9 patients, one with 7, seven with 5, eleven with 4, thirty-two with 3 and Seventy-four with 2 patients. Of the prescribers with 12 through 5 instances of involvement, they were generally the prescriber of both benzodiazepine and Z-drug.

Recommendation: Edits will be placed in the system to require prior authorization for patients on multiple benzodiazepines or in combination with a Z-drug when being utilized concurrently for greater than 60 days.

Board Action: After the Board's discussion, the edit will be placed requiring a PA for patients on multiple benzodiazepines concurrently for greater then 60 days. Edits will be placed in the system to require prior authorization for patients on multiple benzodiazepines or in combination with a Z-drug when being utilized concurrently for greater than 60 days for new starts only. GHS will bring back more information on quantity limits on Z-drugs.

c) Appropriate use of Asthma controller medications

- For anyone who requires use of a short acting agent ≥ 2 days/week, it is recommended to consider adding or changing to daily controller medication. The National Institute of Health Guidelines state that the frequency of short acting beta adrenergic inhalers (SABA) use can be clinically useful as a measure of disease activity since increased use of a SABA has been associated with increased risk for death or near death in patients who have asthma. Use of more than one SABA canister every one to two months is also associated with an increased risk of an acute exacerbation.

Recommendation: GHS will review Vermont paid non-reversed pharmacy and medical claims with dates of service from 7/1/2014 through 6/30/2015 and will exclude

members who have a diagnosis of cystic fibrosis, chronic obstructive pulmonary disease or emphysema and report the following:

1.) Number of unique members broken out by age at first Rx with < 12 inhalers in 12 months vs those with 12-15, 16-19 and ≥ 20 over the 1 year period.
2.) For each sub-group, break out the number with and without at least one ICS and/or leukotriene receptor antagonist claim.
3.) For each group, report the number of hospital admissions and ER visits for asthma related diagnoses.

Board Action: The Board approved the above recommendation with the addition of breaking it down by hospital service area for the February meeting.

7. Clinical Update: Drug Reviews: Mike Ouellette, RPh, GHS/Change Healthcare & Laureen Biczak, DO GHS/Change Heathcare

Abbreviated New Drug Reviews

a) Fycompa®Tab (perampanel)

Recommendation: PDL placement and criteria will be recommended when the Therapeutic Class Review (TCR) is examined.

Public Comment: No public comment.

Board Decision: Defer decision - to occur with the class review.

Full New Drug Reviews:

a) Aptensio XR® Cap (methylphenidate extended-release)

- Methylphenidate, the active ingredient of Aptensio® XR, is a central nervous system (CNS) stimulant. Aptensio® XR, as it contains methylphenidate, is classified as a Schedule II controlled substance and has a high potential for abuse and dependence. Aptensio® XR has a box warning regarding the increased potential for abuse and dependence with use. It is indicated for the treatment of Attention Deficit Hyperactivity Disorder (AHDH). Prior to starting treatment with CNS stimulants, including Aptensio® XR, it is recommended to assess for the presence of cardiac disease.

Recommendation: It is recommended that Aptensio XR® be placed in the non-preferred position on the Preferred Drug List (PDL) requiring prior authorization.

Clinical Criteria:

- Add to the methylphenidate CR clinical criteria.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

b) Glatopa® Inj (glatiramer)

- Glatopa® is indicated for the treatment of patients with relapsing forms of MS. It is considered to be a substitutable generic equivalent to Copaxone® 20mg/ml as Glatiramer acetate is also the active ingredient of Glatopa®. This is a pregnancy category B medication. The recommended dosage is inject 20mg SC once daily. There were 4 placebo-controlled trials performed to assess the safety and efficacy of glatiramer acetate injection of 20mg/ml.

Recommendation: The recommendation is to add Glatopa® 20mg to non-preferred with quantity limits of 30 syringes/30 days.

Clinical criteria:

- Patient is ≥ 18 years AND Diagnosis of relapsing forms of Multiple Sclerosis AND The provider provides a clinically compelling reason why Copaxone 20mg cannot be prescribed

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

c) Invega Trinza® Extended- Release Inj (paliperidone)

- Invega® Trinza, is an atypical antipsychotic. The active ingredient is Paliperidone palmitate. It is indicated as a 3-month injection for the treatment of schizophrenia in patients after they have been adequately treated with Invega® Sustenna (1-month paliperidone palmitate extended-release injectable suspension) for at least 4 months. There are no available data on Invega® Trinza use in pregnant women to inform any drug-associated risk for birth defects or miscarriage. Invega® Trinza has not been studied in patients with renal impairment; however, it is recommended for mild renal impairment to adjust the dose and stabilize the patient using the 1-month paliperidone palmitate ER injection and then transition to Invega® Trinza.

Recommendation: The recommendation is to add Invega® Trinza to non-preferred with the FDA maximum recommended dose= 819mg/3months.

Clinical criteria:

- The patient has been started and stabilized on the medication OR medical necessity for a specialty dosage form has been provided(noncompliance with oral medications) AND tolerability has been established previously with oral/injectable risperidone or oral paliperidone AND Invega Sustenna for at least three months AND only when the dose has been stable over the prior two months.

- Remove grammatical error under Abilify Maintena: Document clinical information supporting the prescribing of Quetiapine in doses of <50mg/day on a Quetiapine Prior Authorization Request Form.
- Remove grammatical error under Saphris: Prior therapy with injectable Invega Sustenna® is not considered to be started and stablilized for oral Invega. Patients transferring to oral therapy from Invega Sustenna® should transition to oral risperidone unless, patient previously failed such treatment.

Public Comment: Arlene Price, J & J: Highlighted some of the attributes of Invega® Trinza. She also asked that the board consider simplifying the criteria to state that all criteria listed must be met for Invega Sustenna, then the criteria for Invega Trinza would simply be that the patient must be stable on Invega Sustenna for at least 4 months.

Board Decision: The Board unanimously approved the above recommendation with no additional changes.

Irenka® Cap (duloxetine)

- Duloxetine, the active ingredient of Irenka®, is a selective serotonin and norepinephrine reuptake inhibitor (SNRI). Duloxetine has been approved for several years under the brand name of Cymbalta® and more recently as a generic, and is available in a capsule formulation in 20mg, 30mg, and 60mg strengths. Irenka® is a 40mg capsule with the same indications as Cymbalta® except for fibromyalgia. There is no evidence to support that Irenka® is safer or more effective than the currently available, more cost effective versions of the same drug.

Recommendation: The recommendation is to add Irenka® to non-preferred with the FDA maximum recommended dose= 120mg/day (MDD and GAD), 60mg/day all others Quantity limit = 2 capsules/day.

Clinical Criteria:

- Remove Cymbalta from the Cymbalta, Duloxetine clinical criteria and adjust criteria to reflect this change.
- Add Cymbalta, Irenka: Must meet criteria for duloxetine (above) AND have a clinically compelling reason why the dosing needs cannot be accomplished with generic duloxetine.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

d) Qudexy XR® (Topiramate extended-release)

Recommendation: PDL placement and criteria will be recommended when the Therapeutic Class Review (TCR) is examined.

Public Comment: No public comment.

Board Decision: Defer decision - to occur with the class review.

e) Stiolto Respimat® Inhaler (tiotropium & olodaterol)

- Stiolto® Respimat is a combination product containing tiotropium and olodaterol. Tiotropium is a long-acting anticholinergic agent that works by inhibition of M3-receptors at the smooth muscle, leading to bronchodilation. Olodaterol is a long-acting beta2-adrenergic agonist (LABA) that binds and activates beta2 receptors, leading to relaxation of airway smooth muscle cells. It is indicated for the long-term, once-daily maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema. Stiolto® Respimat is NOT indicated to treat acute deteriorations of COPD and is NOT indicated to treat asthma. The safety and efficacy of this combination product were assessed in 3 dose ranging trials, 2 active-controlled trials, 3 active- and placebo-controlled trials, and one placebo-controlled trial; however, the efficacy is based primarily on two dose-ranging trials and two confirmatory active-controlled trials. There is no evidence at this time to support that Stiolto® Respimat is more efficacious or safer than the currently available, more cost effective combination products or single products used in combination.

Recommendation: The recommendation is to add Stiolto Respimat® to non-preferred with quantity limit = 1inhaler/30 days.

Clinical Criteria: Add Stiolto® Respimat to the Anoro Ellipta clinical criteria and add the following to bullets:

- Mild-Moderate COPD- failure of individual and combination therapy of one preferred Long Acting Beta Adrenergic (LABA) and a preferred Long Acting Anticholinergic OR
- Severe COPD- failure of one preferred Inhaled Corticosteroid/LABA combination product and the preferred Long Acting Anticholinergic.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

f) Tivorbex® Cap (indomethacin)

- Indomethacin, the active ingredient of Tivorbex®, is an indole derivative NSAID that has analgesic and antipyretics properties. It is indicated for the treatment of mild to moderate acute pain in adults. This is a pregnancy category C medication prior to 30 weeks gestation and a pregnancy category D medication starting at 30 weeks gestation. The safety and efficacy of use in children ≤17 years have not been established. Two multicenter, randomized, double-blind, placebo-controlled trials (N=835 total) were performed to assess the safety and efficacy of Tivorbex® in patients with pain following bunionectomy.

Recommendation: The recommendation is to add Tivorbex® to non-preferred with a quantity limit = 3 capsules/ day.

Clinical Criteria:

- Patient has had a documented side effect, allergy, or treatment failure to 4 more preferred generic NSAIDs, including generic indomethacin.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

8. Therapeutic Drug Classes- Periodic Review: Mike Ouellette, RPh, GHS/Change Healthcare & Laureen Biczak, DO GHS/Change Heathcare

a) Anticonvulsants

- In this category, Qudexy XR® was presented as a new drug.
- New indication for Fycompa as adjunctive therapy for primary generalized tonic-clonic (PGTC) seizures in patients with epilepsy 12 years of age and older.

Recommendation: It is recommended that Qudexy XR® be placed in the non-preferred position on the Preferred Drug List requiring prior authorization, and that the clinical criteria for Fycompa be modified as follows. In addition, the following recommendations for changes to clinical criteria in this class were made:

Clinical Criteria:

- Fycompa® new indication, add to clinical criteria- OR diagnosis is adjunctive therapy for primary generalized tonic-clonic seizures (Fycompa only) AND
- Qudexy XR® add to non-preferred
- Move Topiramate ER to preferred
- Remove Trokendi XR from current criteria and replace with patient has failed treatment with topiramate ER
- Under the clinical criteria for Lyrica caps, Lyrica oral sol add - OR if the diagnosis is for post-herpetic neuralgia or neuropathic pain, there is a

documented side effect, allergy or treatment failure to TWO drugs from the following: tricyclic antidepressant, gabapentin, or SNRI

- In the Restless Leg Syndrome category move Neupro to preferred and remove the current clinical criteria. Add ”two preferred dopamine agonists (pramipexole IR, ropinirole IR, Neupro) AND gabapentin IR” to the Horizant clinical criteria. Also move gabapentin IR to preferred.

Public Comment: Marjory Levey, UCB, : Highlighted some of the attributes of Vimpat®.

Board Decision: The Board unanimously approved the above recommendations.

b) Bladder Relaxants Preparations

- No new drugs.
- No clinically significant changes.

Recommendation: Remove Sanctura, Sanctura XR and Ditropan from PDL and clinical criteria as they are no longer available or rebatable.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

c) BPH Agents

- No new drugs.
- No clinically significant changes.

Recommendation: No change to category.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

d) Epinephine, Self- Injected

- Auvi-Q has been discontinued due to the product not always delivering the full dose intended and it is recommened that people get a new prescription for an alternative product.
- No other clinically significant changes.

Recommendation: No change to category.

Public Comment: Amy Tornasello, Mylan: Highlighted some of the attributes of Epipen®.

Board Decision: None needed.

e) Hyperuricemia & Gout

- No new drugs.
- A 2014 Cochrane Review that included 11 randomized or quasi-randomized controlled trials to assess for the safety and efficacy of allopurinol as compared with placebo or other urate-lowering therapies for the treatment of chronic gout was discussed. The study suggested that the clinical impacts were modest at best, despite lowering of serum urate levels.
- Another 2014 Cochrane Review that was also discussed included two randomized controlled trials to assess for the benefits and harms of colchicine for the treatment of acute gout. Per one study with low-quality evidence, results suggested that there were no additional benefits with high-dose vs low-dose for the primary outcome.
- No clinically significant changes.

Recommendation: It is recommended that colchicine tablets (Colcrys) and colchicine capsules be placed in the non-preferred position on the Preferred Drug List requiring prior authorization.

Clinical Criteria:

- Add colchichine tablets to the Colcrys criteria.
- Remove Krystexxa from PDL and clinical criteria as it is no longer available or rebatable.
- colchicine capsules: The diagnosis or indication for the requested medications is prophylaxis of gout flares in adults AND the patient has had a documented side effect or treatment failure with at least one drug from the NSAID class OR the patient is not a candidate for therapy with at least one drug from the NSAID class due to one of the following: The patient is 60 years of age or older, Patient has a history of GI bleed, Patient is currently taking an anticoagulant (warfarin or heparin), Patient is currently taking an oral corticosteroid, Patient is currently taking methotrexate.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

f) IBS/SBS/Selected GI Agents

- Since the last class review Movantik has been added to the class review, however the board recently did a new drug review and there is no new information.
- The 2014 ACG recommendations for chronic idiopathic constipation include discussions of the use of fiber, but with a low quality of evidence.They also recommend 5-HT_3 antagonists as IBS treatment with a high quality of evidence as

well as mentioning some evidence for the efficacy of antispasmodics as a class. However, since all studies are placebo controlled, the most appropriate place in therapy amongst the various drugs cannot be readily drawn.

- No clinically significant changes.

Recommendation: It is recommended to change the name of the PDL category to Gastrointestinal Agents- Constipation/Diarrhea, Irritable Bowel Syndrome-Constipation, Short Bowel Syndrome, Opioid Induced Constipation. On the preferred side under Osmotic Laxatives remove –compare to Miralax®. Add the drug name Fulyzaq to the clinical criteria. Current criteria for the Growth Stimulating Agents was presented due to Zorbtive being in the class review. However, no changes were made to the category.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation with the addition to add dicyclomine to the PDL and bring it back for January's meeting.

g) Smoking Deterrents

- No new drugs.
- No clinically significant changes.
- A 2015 systematic review included 39 randomized controlled trials to assess the safety and risk of neuropsychiatric adverse events and death associated with Chantix® as compared to placebo. It was concluded that this meta-analysis did not find any evidence of an increased risk of suicide or attempted suicide, suicide ideation, depression, or death with Chantix compared with placebo.
- In March 2015, the FDA disseminated a drug safety communication regarding post-marketing reports of Chantix® changing the way people react to alcohol. Unusual and sometimes aggressive behavior was noted. The prescribing information has been updated to describe this risk of reaction and it is recommended that alcohol consumption should be reduced while taking Chantix®, until it is known whether Chantix® affects one's tolerance for alcohol.

Recommendation: It is recommended to remove Commit Lozenge® from the PDL, as it is no longer available or rebatable.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

9. New managed Therapeutic Drug Classes

- None at this time.

10. Review of Newly-Developed/Revised Clinical Coverage Criteria and/or Preferred Products

- None at this time.

11. General Announcements Mike Ouellette, RPh, GHS/Emdeon

- Selected FDA Safety Alerts

  Invokana and Invokamet (canagliflozin): Drug Safety Communication - New Information on Bone Fracture Risk and Decreased Bone Mineral Density
  http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm461876.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

  Acetaminophen Tablets by Medline Industries: Recall - Mislabeling with Incorrect Strength
  http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm467076.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

  FDA alerts prescribers and pharmacists to continue clozapine prescribing and dispensing if they encounter online Clozapine REMS certification issues
  http://www.fda.gov/Drugs/DrugSafety/ucm467560.htm

  FDA Drug Safety Communication: FDA warns of serious liver injury risk with hepatitis C treatments Viekira Pak and Technivie
  http://www.fda.gov/Drugs/DrugSafety/ucm468634.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

  FDA Drug Safety Communication: FDA requires drug interaction studies with potassium-lowering drug Kayexalate (sodium polystyrene sulfonate)
  http://www.fda.gov/Drugs/DrugSafety/ucm468035.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

  FDA Drug Safety Communication: FDA review found no increased cardiovascular risks with Parkinson's disease drug entacapone
  http://www.fda.gov/Drugs/DrugSafety/ucm468803.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

  FDA Drug Safety Communication: FDA cautions about dose confusion and medication error with antibacterial drug Avycaz (ceftazidime and avibactam)
  http://www.fda.gov/Drugs/DrugSafety/ucm463248.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

FDA Drug Safety Communication: FDA evaluating the risks of using the pain medicine tramadol in children aged 17 and younger
http://www.fda.gov/Drugs/DrugSafety/ucm462991.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

CDEF conversation: Safe medicine disposal options
http://www.fda.gov/drugs/newsevents/ucm464197.htm

Auvi-Q (epinephrine injection, USP): Recall - Potential Inaccurate Dosage Delivery
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm470010.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

FDA Drug Safety Communication: FDA review finds long-term treatment with blood-thinning medicine Plavix (clopidogrel) does not change risk of death
http://www.fda.gov/Drugs/DrugSafety/ucm471286.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

- A discussion ensued about the Safety Alert for tramadol for patients age 17 and younger, and a recommendation was made to add an age edit alerting pharmacies when tramadol is prescribed in children.

    - **Board Decision:** To place age limits on Tramadol for the immediate release which is not FDA approved in patients under 16 years of age and for the extended release which is not FDA approved in patients under 18 years of age.

13. Adjourn: Meeting adjourned at 8:32 p.m.